

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

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<b>IN RE ETHICON, INC., PELVIC REPAIR</b>	<b>:</b>
<b>SYSTEM PRODUCTS LIABILITY</b>	<b>:</b>
<b>LITIGATION</b>	<b>:</b>
-----	<b>MDL No. 2327</b>
	<b>:</b>
	<b>:</b>
This Document Applies To All Actions	Judge Joseph R. Goodwin
	<b>:</b>
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**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A FINDING OF  
SPOLIATION AND FOR SANCTIONS**

Since the inception of this MDL proceeding in 2012, Ethicon, Inc. (“Ethicon” or “the Company”) has produced millions of pages of documents from hundreds of custodians and non-custodial document sources. It has also produced scores of witnesses for deposition and responded to hundreds of written discovery requests. In Spring 2013, attorneys for Ethicon discovered that certain Company employees’ electronic documents were inadvertently not retained upon the employees’ departure from the Company despite Ethicon’s clear, written document retention policies. After some investigation, Ethicon determined that the inadvertent deletion of these materials resulted primarily from a misunderstanding by certain employees regarding who was responsible for retaining documents potentially relevant to litigation at the end of an employee’s tenure at Ethicon. Ethicon’s counsel alerted the MDL plaintiffs to the issue immediately and, since that time, have worked diligently to investigate and remedy the problem. Ethicon also offered James Mittenthal, its corporate representative, to provide multiple depositions regarding his in-depth investigation of Ethicon’s document retention policies and the circumstances that led to the inadvertent loss of materials. Mr. Mittenthal has testified that many of the documents that were lost are available elsewhere in Ethicon’s substantial production.

Nonetheless, plaintiffs have filed an over-reaching motion for default judgment and other severe penalties that exaggerates the scope of the issue by focusing on custodians who separated from the Company years ago, before there was any legal obligation to preserve materials in connection with this litigation and by presuming that documents were improperly destroyed any time an employee's custodial file contains fewer documents than plaintiffs think it should. Putting aside all of plaintiffs' overblown rhetoric, the inadvertent loss of certain Ethicon employees' documents in the context of Ethicon's substantial document production does not justify spoliation sanctions.

**First**, Ethicon did not have a duty to preserve files belonging to many of the employees identified by plaintiffs because of the timeframe during which they left the Company. **Second**, sanctions are also inappropriate because the failure to preserve was unintentional and Ethicon thus lacked a "culpable" state of mind. The Company made substantial efforts to employ litigation holds and, as a result, retained and produced millions of pages of documents potentially relevant to this litigation. The fact that certain individuals mistakenly failed to follow written retention procedures upon leaving Ethicon does not demonstrate "culpable" conduct on the part of the Company. **Third**, plaintiffs cannot establish that evidence relevant to their claims was lost. In fact, thousands of documents to or from the individuals about whom plaintiffs complain were produced through other sources. Plaintiffs' claims in this litigation will turn on: (1) whether the products at issue are defective; (2) whether they carried appropriate warnings; and (3) whether they caused the specific injuries alleged by the bellwether plaintiffs. Plaintiffs have no basis – other than sheer speculation – for their contention that they lack any materials relevant to these key questions. And **fourth**, even if the Court were to determine that a sanction were required, plaintiffs' requests for a default judgment, the striking of defenses and adverse jury

instructions are far too extreme because plaintiffs cannot demonstrate “bad faith,” “extreme prejudice” or “intentional” misconduct.

To be clear, Ethicon is extremely troubled that certain employees did not follow written retention procedures, and the Company takes plaintiffs’ concerns very seriously. Ethicon continuously takes steps to improve its retention procedures and – since discovering this problem – has instituted a number of additional policies and procedures to minimize the risk of retention issues arising in the future. The reality is, however, that the overwhelming majority of documents collected in litigation are never used at trial. A recent survey found that the ratio of the average number of discovery pages to the average number of exhibit pages is 1,044 to 1. *See* Lawyers for Civil Justice, Civil Justice Reform Grp. & U.S. Chamber Inst. for Legal Reform, Litigation Cost Survey of Major Companies 16 (2010), <http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Duke%20Materials/Library/Litigation%20Cost%20Survey%20of%20Major%20Companies.pdf>. Thus, the fact that plaintiffs might have obtained more documents – in addition to the millions they already have – does not mean, by any stretch, that the lost documents have impeded plaintiffs’ efforts to prosecute this litigation. Indeed, the facts suggest precisely the opposite.

For all of these reasons, discussed further below, plaintiffs’ motion should be denied.<sup>1</sup>

## **BACKGROUND**

### **A. The MDL Plaintiffs’ Claims**

This MDL proceeding was created on February 7, 2012 to address claims related to approximately a dozen of Ethicon’s pelvic mesh products, including Ethicon’s TVT and Prolift

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<sup>1</sup> Ethicon has requested oral argument on plaintiffs’ motion, and the parties are working with the Court to identify a mutually agreeable date for such argument.

products. *See In re Am. Med. Sys., Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 844 F. Supp. 2d 1359 (J.P.M.L. 2012). Plaintiffs in the MDL proceeding, including Carolyn Lewis, who has been selected as the first bellwether-trial plaintiff, allege personal injury claims based on their use of these products. (*See, e.g.,* Compl., *Lewis v. Johnson & Johnson*, No. 2:12-cv-04301, Dkt. No. 1 (July 25, 2012).) According to plaintiffs, the material from which the products are made is “biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Pelvic Mesh Products.” (*Id.* ¶ 18.) Plaintiffs claim that “[w]hen mesh is inserted in the female body according to the manufacturers’ instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.” (*Id.*) Plaintiffs further allege that defendants “omitted the risks, dangers, defects, and disadvantages of the Pelvic Mesh Products, and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as safe medical devices when Defendants knew or should have known that the Pelvic Mesh Products were not safe for their intended purposes.” (*Id.* ¶ 39.) Based on these allegations, plaintiffs allege a variety of product-liability causes of action, including claims for negligence, strict liability (design defect, manufacturing defect and failure to warn) and breach of express and implied warranties. (*Id.* ¶¶ 65-110.)

#### **B. The History Of The Litigation**

Before 2008, only a handful of isolated cases addressing Ethicon’s pelvic mesh products were filed in state courts, some of which included medical malpractice claims. (*See* Decl. of Benjamin M. Watson (“Watson Decl.”) ¶¶ 2-3 (attached as Ex. 1).) Discovery in these cases, if any, was comprised of general source materials. (*Id.* ¶ 3.) Nonetheless, in an abundance of caution, Ethicon issued litigation holds with respect to three cases that involved certain TVT products. (*Id.*)

In 2008, approximately five pelvic mesh cases were filed in state court in New Jersey. (*Id.* ¶ 4.) While a litigation hold notice was issued in connection with one of these cases in April 2008 (*id.*), the very small number of cases pending at that time did not constitute a critical mass of cases alerting Ethicon to the widespread litigation that would come in the following years. Again, document production was comprised of general source materials in 2008. (*Id.*) More than two years later, on October 12, 2010, the New Jersey Supreme Court ordered the centralized management of the pending pelvic mesh cases in New Jersey state court involving Ethicon and its parent company, Johnson & Johnson (“J&J”). (*Id.* ¶ 5.) It was only after centralized management of the New Jersey state court actions that the pelvic mesh litigation “began to pick up speed.” (*Id.* ¶ 6.) Between October 14, 2010 and February 6, 2012, approximately 400 pelvic mesh cases were filed in New Jersey state court. (*Id.*) “In contrast to the prior trickle of cases, this large number of filings signaled the creation of a mass tort.” (*Id.*) By early 2012, there were approximately 54 cases involving Ethicon’s mesh products pending in federal courts around the country, all of which were transferred to this Court pursuant to the JPML’s order creating this MDL proceeding on February 7, 2012. (*Id.* ¶ 7.)

Based on the timeline of the litigation, any reasonable expectation of litigation capable of triggering a general and widespread duty to preserve and collect documents from a wide range of custodians with respect to a wide range of products did not arise until sometime between 2008 and 2010, when a sufficient number of cases involving the products at issue were pending to warrant consolidated treatment by the New Jersey Supreme Court. At the very earliest, such a generalized duty arose when the first litigation hold notice was issued in a New Jersey case in April 2008.

**B. Ethicon's Document Retention Efforts & Litigation Holds**

Ethicon and its affiliates employ more than 11,000 people worldwide and have offices in more than 50 countries. (*See* Decl. of James P. Mittenthal ("Mittenthal Decl.") ¶ 18 (attached as Ex. 2).) As a medical device manufacturer, Ethicon operates in a "highly regulated environment . . . with respect to record retention" and has established "robust policies, schedules and procedures governing retention that apply even in the absence of litigation." (*Id.* ¶¶ 19-20; *see also* Decl. of Lisa Kaiser ("Kaiser Decl.") ¶¶ 4-5 (attached as Ex. 3).) Pursuant to these policies, Ethicon retains a large volume of documents related to its products, including "design history files (DHF's), laboratory notebooks, technical reports, labeling content and FDA submissions." (Mittenthal Decl. ¶ 22.) Ethicon also has in place significant "training programs and protocols to educate its associates as to record retention." (Kaiser Decl. ¶¶ 11-13.)

In addition to its general document retention policies and training, Ethicon has taken added steps to "promote appropriate record retention in connection with the commencement of litigation regarding its pelvic mesh products," including the issuance of litigation hold notices, which direct employees to retain documents pertaining to filed litigation. (Mittenthal Decl. ¶ 29; *see also* Kaiser Decl. ¶¶ 14-15.) The litigation hold notices issued in the New Jersey and MDL pelvic mesh cases since 2008 have been broad in scope, requiring employees to preserve many categories of materials related to the products at issue, including but not limited to documents regarding: "(1) Labeling; (2) Pharmacovigilance/Quality/Post-Market Surveillance; (3) Regulatory; (4) Discovery, Research and Development and Quality Engineering; (5) Product Communications; (6) Marketing and Sales Material; (7) Professional Education; (8) Manufacturing Documents and Equipment; and (9) Medical Affairs and Clinical Studies; and (10) Distribution." (Mittenthal Decl. ¶ 34.) By 2008, Ethicon had established a centrally-

managed document repository that allowed employees to move documents relevant to litigation into a folder for preservation. (*Id.* ¶ 35.) The litigation hold notices issued at and after this time directed employees how to use these repositories. (*Id.*) However, individual employees were given the flexibility to “manage their information and records in different ways during their employment and at their departure (e.g., using the litigation hold folders, using other folders that are retained, copying materials) that proved most conducive to business use” when complying with litigation holds. (*Id.* ¶ 38.)<sup>2</sup> Ethicon made a “conscientious effort to educate its employees as to their responsibilities to preserve information” pursuant to the hold notices and requires employees to complete annual training on legal hold notices. (*Id.* ¶ 40.) Specifically, Ethicon required its employees to complete annual training that explains what hold notices are, how to read them, and their legal ramifications – and then tests the employees on that information. (Kaiser Decl. ¶¶ 14-15; Mittenthal Decl. ¶ 42.)

In addition to requiring its employees to comply with litigation holds on an ongoing basis, Ethicon has also had in place, at all relevant times, a written procedure for preserving documents relevant to litigation when employees leave the Company. Pursuant to Company policies, the departing employees’ managers are responsible for instructing the employees to review their “electronic files against any Preservation Notices in effect.” (Mittenthal Decl. ¶ 46.) Departing employees are also responsible for working with their managers to complete an “Exit Checklist & Certificate of Compliance For Records Disposition” prior to leaving the Company

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<sup>2</sup> Plaintiffs claim that “Ethicon has not had a written policy regarding document retention at any time relevant to this motion.” (Mot. at 12.) That statement is untrue, as explained above. Plaintiffs also argue that Ethicon’s litigation hold policies were “ineffective” because employees were not “required” to use centralized litigation hold folders. (*Id.*) However, as Mr. Mittenthal has explained, Ethicon’s practice of providing litigation hold folders as a resource, while allowing employees to determine which retention method is most convenient, is consistent with the well-founded philosophy that an individual is in the best position to understand and manage his or her information and records. (Mittenthal Decl. ¶¶ 36-38.)

that instructs employees to preserve any documents that have been retained for litigation. (*Id.*) The Company's Information Technology ("IT") department was responsible for transferring the departing employee's electronic files to a CD before repurposing the employee's hard drive only if it was required by the employee's manager. (*Id.*)

**C. Problems Identified During Document Collection Efforts**

Despite the document retention and litigation hold policies outlined above, discovery conducted in the MDL proceeding over the course of the last year has revealed that proper steps were not taken to preserve electronic files when certain employees who have been identified as "custodians" of documents potentially relevant to the pelvic mesh litigation left the Company. (*See* Mittenthal Decl. ¶¶ 47-50.) Ethicon's attorneys discovered this issue in Spring 2013 in connection with a massive custodial collection effort, and upon learning of the lack of electronic files for certain employees, immediately alerted plaintiffs' counsel to the problem and offered a deposition to assist plaintiffs in understanding the underlying facts. (*See* Ex. Z to Pls.' Mem. In Supp. of Mot. For Sanctions.) As additional issues were later identified, counsel for Ethicon again reached out to plaintiffs to advise them of their findings.

In an attempt to determine why certain former employees' electronic files were not preserved upon their departure from the Company, Ethicon asked James Mittenthal, its retained 30(b)(6) representative regarding e-discovery efforts, to conduct an investigation into the issue. Pursuant to his investigation, Mr. Mittenthal concluded that, for most of the former employees at issue, "the employee understood and properly preserved documents while working at Ethicon," but electronic files were nonetheless lost because "upon the employee's departure or separation from the company, his or her electronic data were not properly transferred . . . [and] the contents of the employee's hard drive were not preserved." (Mittenthal Decl. ¶ 50.) According to Mr. Mittenthal, this occurred because of a misunderstanding on the part of either the employee, who



“assumed” everything on his or her hard drive would be preserved and failed to identify relevant materials for his or her manager, or the manager, who did not effectively communicate to IT that certain materials on the employee’s hard drive needed to be preserved. (*Id.*) Mr. Mittenthal also noted that in other, “rare circumstances,” electronic data were lost “because the former employee misunderstood the requirements to preserve documents, notwithstanding the litigation hold notices issued.” (*Id.*)

In their motion, and the supplement to that motion filed nearly a month later, plaintiffs identify 22 current and former Ethicon employees who they claim did not properly preserve electronic documents (or whose documents were not properly preserved when the employees left the Company), including: Renee Selman, the former president of Ethicon’s Women’s Health & Urology business; a number of employees in the clinical, medical, marketing and regulatory departments; and two sales representatives. (*See* Pls.’ Mem. In Supp. of Mot. For Sanctions (“Mot.”), Dkt. No. 953, at 3-9; Pls.’ Notice of Supplement In Supp. Of Mot. For Sanctions (“Supplement”), Dkt. No. 996, at 1-4.) However, 13 of these individuals left Ethicon before 2008, the earliest possible date that Ethicon could have had a general obligation to preserve documents on a widespread basis with respect to the pelvic mesh products at issue in this litigation.<sup>3</sup> In addition, a number of the individuals identified by plaintiffs would not have had a significant number of documents related to this litigation in their personal files because of the nature of their roles with the Company. (Mittenthal Decl. ¶¶ 81, 84.) For example, Mr.

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<sup>3</sup> These individuals include Rick Isenberg (departed 2002), Gregory Jones (departed 2003), Amy Godwin (departed 2004), Charlotte Owens (departed 2005), Sean O’Bryan (departed 2005), Laura Angelini (departed 2005), Kendra Munchel (departed 2005), Zenobia Walji (departed 2005), Jill Schiaparelli (departed 2005), Patricia Hojnoski (departed 2006; returned in 2008 as contract employee with limited administrative responsibilities for one year), Cheryl Bogardus (departed 2007), Allison London Brown (departed 2007), and John Clay (departed 2007). (*See* Mittenthal Decl. ¶ 61). As discussed in Mr. Mittenthal’s declaration, plaintiffs have misstated the dates of employment for some of these individuals by including periods of time when they were working for other entities. (*Id.*)

Mittenthal noted that it is “unsurprising” that “relatively few documents were directly collected from sales representatives such as Paul Courts and Troy Mohler” because the “role of a medical device sales representative at Ethicon is not document-intensive.” (*Id.* ¶¶ 81-82.) Another individual listed by plaintiffs, Susanne Landgrebe, experienced a crash of her hard drive in 2009, after her involvement with pelvic mesh products ended. (*Id.* ¶ 84.) Therefore, Ms. Landgrebe’s pre-2009 documents are no longer accessible. (*Id.*)<sup>4</sup> Other employees’ custodial files may be missing documents for other, similar reasons that have nothing to do with a failure to follow the Company’s preservation notices, as set forth in more detail in Mr. Mittenthal’s declaration. (*Id.*)

Notably, Ethicon has produced documents and communications to and from the 22 individuals identified in plaintiffs’ motion from multiple sources other than their own files. As Mr. Mittenthal explains, the fact that a specific former employee’s individual “custodial file” contains few or no documents does not mean that few or no documents related to that individual were produced in this litigation. (*Id.* ¶¶ 70-73.) This is because an employee’s “custodial file” merely includes documents that were collected directly from that employee’s individual hard copy or electronic files. (*Id.* ¶ 65.) Since employees regularly store documents in other “common source” locations – or transfer documents to those locations – Ethicon was still able to produce documents from employees whose custodial files were not fully preserved. (*Id.* ¶¶ 66-69.)

Importantly, the documents that will be most relevant to plaintiffs’ product-liability claims, i.e., documents pertaining to the product design, regulatory documents, marketing materials, complaints regarding pelvic mesh products and other post-market surveillance

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<sup>4</sup> Susanne Landgrebe recently located an old personal hard drive, which she was unaware she had. Ms. Landgrebe believes it may contain some work-related documents, which she believes would likely be duplicative of documents already produced from other sources. Ethicon is in the process of obtaining these documents and will produce responsive documents, if any.

evidence, are maintained centrally at Ethicon – not in individual custodian files – and have been collected and produced. (*Id.* ¶ 68; *see also* Kaiser Decl. ¶ 17.) Thus, for example, while plaintiffs complain that they have only 20 documents for Gregory Jones even though he “kept electronic copies of . . . 510ks . . . FDA correspondence” and other regulatory materials (Mot. at 7), plaintiffs ignore the fact that such regulatory submissions, correspondence and documents are stored in common files and “have been produced from the appropriate central sources of record.” (Mittenthal Decl. ¶ 84.)

In addition, many employees store their documents in central electronic filing locations, such as shared “L drives” on the Company’s computer system, which were searched for relevant documents in connection with Ethicon’s document production. (*Id.* ¶ 69.) Moreover, because Ethicon employees work collaboratively, electronic documents created or received by one employee are often found in the files of another employee with whom he or she worked. In fact, a search of Ethicon’s production thus far revealed that the Company has produced hundreds – and, in the overwhelming majority of cases, thousands – of emails and corresponding attachments to or from *each of the 22 individuals* identified in plaintiffs’ motion as having few or no electronic files. (*Id.* ¶ 70.) By way of example, Ethicon has produced approximately 8,503 of Renee Selman’s emails and attachments, 17,125 of Price St. Hilaire’s emails and attachments, 4,430 of Nancy Leclair’s emails and attachments, 5,520 of Cheryl Bogardus’s emails and attachments and 14,651 of Allison London Brown’s emails and attachments. (*Id.*)

Thus, “even where an individual’s ‘custodial file’ does not contain any documents, as shown above,” it is likely that many of the “individual’s documents (including email communications) have been collected and produced from file shares, databases, and other enterprise electronic systems, as well as from other individuals’ ‘custodial files.’” (*Id.* ¶ 73.)

**D. Ethicon's Efforts To Prevent Loss Of Electronic Files Going Forward**

Ethicon examines its policies, training and technology with respect to document retention on an ongoing basis and makes efforts to improve them, where appropriate. (Mittenthal Decl. ¶ 51.) In the last year, and especially since learning that some electronic documents were not preserved upon the departure of certain former employees, Ethicon has implemented a number of additional retention measures “to secure its ability to meet legal hold obligations going forward.” (*Id.* ¶ 52.) For example:

- In June 2012, Ethicon began saving all hard drives of employees who depart the Company. (*Id.* ¶ 56.)
- In December 2012, the third-party vendor that manages the hardware of all Ethicon sales representatives began permanently retaining all hard drive images when a sales representative separates from the Company (or receives replacement equipment). (*Id.* ¶ 53.) Ethicon also took a series of steps to “educate sales representatives as to compliance with litigation hold notices.” (*Id.* ¶ 54.)<sup>5</sup>
- In early 2013, Ethicon joined the “IT Safe” program, under which the hard drive of every employee who leaves the Company is shipped to the IT shared services group for imaging to preserve all information contained therein. (*Id.* ¶ 56.)
- In 2013, Ethicon also launched Outlook Exchange 2010, which allowed emails to be saved permanently in a central location, thereby permitting “more centralized management and storage of documents that have traditionally resided with individual custodians.” (*Id.* ¶ 55.)

**E. Plaintiffs' Other Discovery-Related Allegations**

Plaintiffs also claim in their motion that Ethicon “destroyed” other evidence relevant to their claims, including: (1) “600 pounds of documents” from MedScand, the original manufacturer of the TVT product; and (2) videos allegedly prepared by Dr. Todd Heniford regarding light-weight mesh products. (Mot. at 9-10.) Neither allegation is true.

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<sup>5</sup> Plaintiffs argue that these efforts to educate sales representatives regarding the Company's retention policies are akin to an admission that “Ethicon employees' understanding of the litigation hold process was . . . faulty.” (Mot. at 14-15.) The Court should not accept this “damned if you do, damned if you don't” argument.

1. MedScand Documents

MedScand is a Swedish company, not affiliated with Ethicon or J&J, that initially manufactured the pelvic mesh product TVT. (*See* Decl. of Pamela Downs (“Downs Decl.”) ¶ 3 (attached as Ex. 4).) In 1999, Ethicon purchased the rights to TVT and began manufacturing the product. (*Id.* ¶ 5.) When MedScand was purchased by Cooper Surgical in 2005, Cooper Surgical sought to transition a pallet containing 12 cases of documents pertaining to TVT to Ethicon. (*Id.*) In 2006, Ethicon determined that seven of the 12 cases that contained product retains (i.e. samples of TVT that were past their shelf life) should be discarded because they “no longer served any business purpose.” (*Id.* ¶ 7.) Expired product retains are not ordinarily kept because they are no longer usable and therefore “no longer serve[] a business function.”<sup>6</sup> (*Id.* ¶ 9.) Four of the 12 cases contained documents pertaining to specific batches of mesh. Records reflect that Ethicon decided to send four cases to Ethicon SARL in Neuchatel, Switzerland, for storage. However, Ethicon has been unable to locate these cases. (*Id.* ¶ 10.) The one remaining case of materials – which contained clinical study information – was shipped to an offsite storage facility maintained by a third-party vendor in Neuchatel, Switzerland in February 2006. (*Id.* ¶ 11.) That facility experienced a fire on or around September 24, 2009, and the majority of the MedScand materials were destroyed. (*Id.* ¶ 12.) The only material that did survive was a binder of patient data that has been produced to plaintiffs. (*Id.*) In addition, Ethicon has produced clinical study information related to TVT that was available from other sources, including materials related to studies performed by Ulf Ulmsten, who was involved in the development of TVT (*id.* ¶ 13), which plaintiffs claim were the “cornerstone” of Ethicon’s marketing for TVT

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<sup>6</sup> Plaintiffs criticize a November 7, 2005 email string in which two Ethicon employees discussed that the seven cases of expired product retains that served no continued business purpose need not be retained unless there was a litigation hold in place. (Mot. at 11.) But this was not an unreasonable conclusion, as retention of expired product retains was not warranted.

(Mot. at 10).<sup>7</sup>

2. Heniford Videos

Dr. Todd Heniford is a consultant for Ethicon. Plaintiffs claim that Dr. Heniford “created several videos for Ethicon” regarding the “benefits of using lighter mesh material,” but that Ethicon has only produced one of those videos. (Mot. at 9-10.) Plaintiffs claim that Ethicon’s failure to produce additional videos indicates that Ethicon “lost or destroyed almost every video produced by Dr. Heniford.” (*Id.* at 9.)

Plaintiffs have offered no evidence that another video discussing lighter-mesh material was ever sent to Ethicon by Dr. Heniford, and based on discussions with Dr. Heniford, Ethicon does not have reason to believe that such a video was even made. Dr. Heniford is in the process of producing documents from his files in this litigation and is scheduled to be deposed on January 24, 2014. Ethicon will promptly review those materials and perform additional searches, as appropriate, if Dr. Heniford’s documents indicate that another video discussing light-weight mesh was ever created.

**ARGUMENT**

A party seeking sanctions based on the alleged spoliation of evidence bears the burden of proving that:

(1) [t]he party having control over the evidence had an obligation to preserve it when it was destroyed or altered; (2) the destruction or loss was accompanied by a culpable state of mind; and (3) the evidence that was destroyed or altered was relevant to the claims or defenses of the party that sought the discovery of the spoliated evidence, to the extent that a reasonable factfinder could conclude that the lost evidence would have supported the claims or defenses of the party that sought it.”

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<sup>7</sup> In addition, Ethicon’s responses to plaintiffs’ 225 Requests For Admission include information regarding payments made to MedScand and Ulmsten that plaintiffs claim was lost. (*See* Mot. at 6 (arguing that Ethicon employees have testified that they “do not know how to locate documentation about Ethicon’s payments to Mr. Ulmsten or Medscand”).)

*Ayers v. Sheetz, Inc.*, No. 3:11-cv-00434, 2012 U.S. Dist. LEXIS 149960, at \*6-7 (S.D. W. Va. Oct. 18, 2012) (internal quotation marks and citation omitted). Although a trial court has a “range of options available” to sanction the spoliation of evidence, any sanction adopted should be narrowly tailored to “serve the twin purposes of leveling the evidentiary playing field and . . . sanctioning the improper conduct.” *Loveless v. John’s Ford, Inc.*, 232 F. App’x 229, 236 (4th Cir. 2007) (internal quotation marks and citation omitted); *see also Silvestri v. Gen. Motors Corp.*, 271 F.3d 583, 590 (4th Cir. 2001) (noting that “the applicable sanction [for spoliation] should be molded to serve the prophylactic, punitive, and remedial rationales underlying the spoliation doctrine”) (internal quotation marks and citation omitted).

Here, Ethicon’s inadvertent loss of documents despite the Company’s significant document retention and legal hold policies and efforts does not constitute spoliation because plaintiffs cannot demonstrate that: (1) Ethicon had a legal obligation to preserve files in the possession of many of the 22 employees identified in plaintiffs’ motion and subsequent supplement; (2) the loss of the documents was the result of any “culpable” conduct by the Company; or (3) the evidence at issue was actually lost and would have supported their claims. Further, even if plaintiffs had proven that spoliation occurred, they have not come close to making the showing of “bad faith” or “willfulness” necessary to justify the extreme sanctions they seek.

# **I. ETHICON DID NOT ENGAGE IN SPOLIATION OF EVIDENCE.**

## **A. Plaintiffs Cannot Prove That Ethicon Had A Duty To Retain Many Of The Documents At Issue In Plaintiffs’ Motion.**

Plaintiffs’ motion should be denied because they seek sanctions for the alleged spoliation of evidence that was lost long before the Company had a duty to preserve evidence in connection with this litigation. A party has a duty to preserve material evidence when the party “reasonably

should know that the evidence may be relevant to anticipated litigation.” *Ayers*, 2012 U.S. Dist. LEXIS 149960, at \*5 (internal quotation marks and citation omitted). Importantly, this duty requires the party only to “identify, locate, and maintain information that is relevant to *specific, predictable, and identifiable* litigation.” *Id.* (internal quotation marks and citation omitted, emphasis added). Consistent with this principle, courts have made clear that the mere existence of other litigation involving a product or course of conduct does not give rise to a general duty to retain documents in all subsequent litigation that may one day arise on the same subject matter. Rather, the duty to preserve documents is “proportional” to the scope of the pending cases. *See, e.g., Rimkus Consulting Grp., Inc. v. Cammarata*, 688 F. Supp. 2d 598, 613 (S.D. Tex. 2010) (a party’s obligation to preserve documents in connection with litigation “depends on what is *reasonable* and . . . what [is]. . . *proportional* to that case”).

For example, in *In re Pradaxa (Dabigatran Etexilate) Products Liability Litigation*, plaintiffs alleged spoliation after the defendant pharmaceutical company (“BIPI”) was unable to produce a custodial file for a former employee who used to be BIPI’s Vice-President of Cardiovascular and Metabolic Disease Marketing. MDL No. 2385, 2013 U.S. Dist. LEXIS 137235, at \*5 (S.D. Ill. Sept. 25, 2013). BIPI contended that the custodial file was destroyed in November 2011 – in accordance with the company’s document retention policies – after the employee left the company, and that there was no spoliation because it did not have a duty to preserve evidence until February 2012, when it received plaintiffs’ demand letter. *Id.* at \*8. Plaintiffs disagreed, arguing that BIPI’s pre-litigation duty to preserve evidence arose in 2008, when BIPI was a defendant in litigation related to a single patient who allegedly suffered an “adverse bleeding event” after using Pradaxa. *Id.* at \*35. This was so, according to plaintiffs, because the “allegations in the [prior] litigation [we]re identical to the allegations at issue in this



MDL and as such triggered a duty to preserve evidence relevant to potential Pradaxa product liability litigation.” *Id.* at \*36. The court rejected this argument, explaining that the prior litigation was “not sufficient to trigger a general preservation obligation” in November 2011, when the Vice-President’s custodial files were destroyed. *Id.* at \*42. Instead, the court held that “the duty to preserve did not arise until February 2012 – when the defendants received a demand letter.” *Id.*; *see also, e.g., Brigham Young Univ. v. Pfizer, Inc.*, 282 F.R.D. 566, 572 (D. Utah 2012) (rejecting plaintiff’s argument that Pfizer’s duty to preserve evidence arose “not only from an awareness of [the present] action” but also from “Pfizer’s litigation with other parties”); *Vasudevan Software, Inc. v. Microstrategy Inc.*, No. 11-cv-06637-RS-PSG, 2013 U.S. Dist. LEXIS 48525, at \*6-7 (N.D. Cal. Apr. 3, 2013) (duty to preserve from prior litigation did not extend to “every possible party who” later was involved in similar litigation, but rather only arose after plaintiff “initiate[d] litigation against Microstrategy”); *Point Blank Solutions, Inc. v. Toyobo Am., Inc.*, No. 09-61166, 2011 U.S. Dist. LEXIS 42239, at \*5 (S.D. Fla. Apr. 5, 2011) (no spoliation claim where “the alleged destruction of evidence arose primarily when Defendants were under a duty to *others* . . . but not necessarily these Plaintiffs”).

Here, plaintiffs’ spoliation motion is based on the assertion that Ethicon had a duty to preserve evidence related to this litigation beginning in 2003 (Mot. at 17), in connection with a pelvic mesh lawsuit filed against Ethicon in Oregon state court. (Watson Decl. ¶ 3.) But that was an isolated, quickly settled case – and it was therefore “not sufficient to trigger a general preservation obligation.” *In re Pradaxa*, 2013 U.S. Dist. LEXIS 137235, at \*42. The same is true with respect to the handful of pelvic mesh cases pending before 2008. Because these cases were limited in scope and duration (Watson Decl. ¶ 3), they did not warrant widespread retention of documents belonging to all of the employees at issue in plaintiffs’ motion. Rather, Ethicon’s

obligation was “proportional” to the scope of those limited cases. *Rimkus*, 688 F. Supp. 2d at 613.

By contrast, Ethicon’s legal obligation to preserve information more broadly arose sometime between April 2008 (at the earliest), when the first litigation hold was issued in connection with one of the New Jersey-filed cases (Watson Decl. ¶ 4), and October 2010 – when the New Jersey Supreme Court ordered the centralized management of all the pending pelvic mesh cases, and the pelvic-mesh litigation “began to pick up speed.” (*Id.* ¶ 6.)

Critically, of the 22 employees identified in plaintiffs’ motion and supplement as having “inadequate” custodial files (*see* Mot. at 3-9; Supplement at 1-4), 13 separated from Ethicon before the first New Jersey litigation hold was issued in 2008. (Mittenthal Decl. ¶ 61 (explaining that Owens, O’Bryan, Angelini, Bogardus, Jones, Hojnoski, Isenberg, Schiaparelli, London Brown, Munchel, Clay, Godwin and Walji left Ethicon before the inception of the current litigation).) Five additional employees, including Renee Selman, left before the New Jersey Supreme Court found that there were sufficient cases pending to warrant consolidation in October 2010. (*Id.* ¶ 63.) Thus, the majority of the employees at issue in plaintiffs’ motion separated from the Company before the obligation to preserve arose. In addition, the majority of the TVT materials from MedScand identified in plaintiffs’ motion were discarded in 2006 because they served no business purpose, and other materials were destroyed in a fire at a third-party facility over which Ethicon had no control. (Downs Decl. ¶¶ 7-11.)<sup>8</sup> Accordingly, much of plaintiffs’ motion is based on the loss of documents that occurred at a time when Ethicon had no duty to retain them – or events Ethicon could not control.

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<sup>8</sup> Further, plaintiffs have no evidence that Ethicon had in its possession – much less destroyed – videos made by Dr. Heniford at *any time*. Obviously, Ethicon cannot be blamed for “losing” materials that it never possessed.

**B. Plaintiffs Cannot Establish That Ethicon Had A “Culpable State Of Mind.”**

Plaintiffs’ motion for sanctions should also be denied because plaintiffs cannot establish that the “destruction or loss [of relevant evidence] was accompanied by a culpable state of mind.” *Ayers*, 2012 U.S. Dist. LEXIS 149960, at \*6 (internal quotation marks and citation omitted). “The three possible states of mind that satisfy this requirement are bad faith destruction, gross negligence, and ordinary negligence.” *Sampson v. City of Cambridge*, 251 F.R.D. 172, 179 (D. Md. 2008). Plaintiffs cannot demonstrate culpability here.

As set forth above, Ethicon has engaged in extensive, good-faith efforts to preserve and produce evidence over the course of this MDL. Indeed, even plaintiffs acknowledge that “Ethicon has issued litigation hold notifications for all of the products covered in this MDL” proceeding. (Mot. at 11.) These hold notices unambiguously instructed employees to refrain from “discard[ing], destroy[ing], or alter[ing] in any way any” documents pertaining to the products at issue in the MDL. (Mittenthal Decl. ¶ 33.) As a result of these preservation efforts, Ethicon has been able to collect and produce millions of pages of documents to plaintiffs. (*Id.* ¶ 10.)

According to plaintiffs, the Court should nonetheless find that Ethicon engaged in “negligence or gross negligence” because the Company “did very little to ensure that documents were actually being preserved” pursuant to its document retention policies. (Mot. at 18-19.) But as the Mittenthal declaration makes clear, Ethicon has made an ongoing effort to educate its employees about their responsibilities to preserve information for litigation purposes. (Mittenthal Decl. ¶¶ 40-43.) For instance, employees were required to complete training on legal hold notices on an annual basis during the relevant period. (*Id.*) In addition, Ethicon’s written procedures required employees leaving the Company to work with their managers to review their electronic files, determine whether any hold notices are in effect and complete an “Exit Checklist

& Certificate of Compliance For Records Disposition” in order to appropriately preserve all documents subject to a litigation hold or other retention policy. (*Id.* ¶ 46.) These efforts plainly show that Ethicon did not act with the requisite “culpable state of mind” necessary to impose sanctions. *See, e.g., Danny Lynn Elec. v. Veolia Es Solid Waste*, No. 2:09CV192-MHT (WO), 2012 U.S. Dist. LEXIS 31685, at \*10-11 (M.D. Ala. Mar. 9, 2012) (defendants not culpable where they had “an effective litigation hold policy in place” despite plaintiffs’ contention that “defendants deleted and failed to preserve thousands of emails and failed to implement an adequate litigation hold”).

Plaintiffs also cannot demonstrate that the Company was “culpable” with respect to the other materials at issue in their motion. For example, plaintiffs argue that Ethicon engaged in spoliation with respect to documents created by MedScand, the original manufacturer of TVT, that are no longer available. (*See* Mot. at 10-11, 18.) However, plaintiffs fail to present any facts suggesting that Ethicon acted negligently with respect to these materials. Instead, plaintiffs merely speculate that “[h]undreds of pounds worth of boxes [of documents] do not get destroyed by accident,” and the “logical inference is that those boxes . . . contained harmful information, leading to their destruction.” (Mot. at 18.) But the facts are to the contrary. As set forth above, the majority of the MedScand materials were appropriately discarded because they consisted mostly of expired product retains and therefore had no business purpose (Downs Decl. ¶¶ 7-9), and retention was not warranted. Other documents were destroyed in a fire at a third-party storage facility over which Ethicon had no control – and any relevant documents that survived the fire were turned over to plaintiffs. (*Id.* ¶ 11.)

Plaintiffs’ allegation that Ethicon negligently or intentionally destroyed videos made by Dr. Heniford is even more far-fetched. (*See* Mot. at 9-10, 21-22.) There is no evidence that

Ethicon received such videos in the first place and therefore no basis to conclude that Ethicon negligently or intentionally “lost or destroyed” them. (Mot. at 9.)

For all of these reasons, plaintiffs cannot demonstrate culpability.

**C. Plaintiffs Have No Proof That Evidence Relevant To Their Claims Is Unavailable.**

Plaintiffs have also failed to present facts from which a “reasonable factfinder could conclude that the lost evidence would have supported the claims . . . of the party that sought” the sanctions. *Ayers*, 2012 U.S. Dist. LEXIS 149960, at \*6-7 (internal quotation marks and citation omitted).

*First*, plaintiffs have not shown that the allegedly lost documents would have supported their claims. The standard for establishing that allegedly spoliated evidence is relevant to the claims at issue is “more substantial than that required to satisfy Rule 401 of the Federal Rules of Evidence.” *Digital Vending Servs. Int’l, Inc. v. Univ. of Phoenix, Inc.*, No. 2:09cv555, 2013 U.S. Dist. LEXIS 145159, at \*20-22 (E.D. Va. Oct. 3, 2013). “[R]elevancy must be proven ‘by offering probative evidence, not the hyperbole of argument.’” *Id.* at \*21 (citation omitted). Thus, “[t]he burden is on the aggrieved party to establish a reasonable possibility, based on concrete evidence rather than a fertile imagination, that access to the lost material would have produced evidence favorable to his cause.” *Sampson*, 251 F.R.D. at 180 (quoting *Gates Rubber Co. v. Bando Chem. Indus., Ltd.*, 167 F.R.D. 90, 104 (D. Colo. 1996)); *see also Huggins v. Prince George’s Cnty.*, 750 F. Supp. 2d 549, 563 (D. Md. 2010) (denying motion for spoliation sanctions where the “Plaintiff had not presented sufficient indications” that the documents allegedly lost were “directly relevant” to the claims at issue), *aff’d*, 683 F.3d 525 (4th Cir. 2012).

Here, plaintiffs have no evidence, much less “concrete evidence,” that any of the materials at issue would have been relevant to their claims. Plaintiffs speculate that “[g]iven the

sheer volume of information that was lost or destroyed, it is unfathomable that none of it would have been relevant to the Plaintiffs' claims." (Mot. at 20.) However, plaintiffs themselves concede that the key questions in their cases will be whether Ethicon's pelvic mesh products were "sold in an unreasonably dangerous condition with insufficient warnings" and whether Ethicon "deceived the Plaintiff[s]" – or their doctors – about the products. (*Id.*) The answers to these questions will undoubtedly turn on evidence that plaintiffs cannot dispute is already within their possession, such as adverse event reports, materials related to the regulatory approval of the products and their warning labels, and marketing materials communicated to doctors and patients. Plaintiffs suggest that because some electronic files on the hard drives of former employees who worked in the areas of regulatory compliance, marketing, and sales were not preserved, the Court should assume that key documents relevant to these subjects were lost. (Mot. at 21-22.) However, as explained in the attached declarations of James Mittenthal and Lisa Kaiser, documents pertaining to these key subjects are maintained centrally at Ethicon – not in individual custodian files – and have already been produced. (Mittenthal Decl. ¶ 68; *see also* Kaiser Decl. ¶ 17.)

Notably, plaintiffs are unable to point to any specific documents relevant to their claims – such as regulatory submissions, adverse event reports, or draft marketing materials – that they claim are missing from Ethicon's substantial production. The closest plaintiffs come to identifying a supposedly relevant, missing document is their argument that Ethicon destroyed videos about light-weight mesh prepared by Dr. Heniford, which plaintiffs claim could be used as "impeachment" evidence in the event that Dr. Heniford testifies in future cases. (Mot. at 21-22.) But plaintiffs admit that Ethicon already produced a video on this subject matter, and they

have offered no evidence that another video presentation discussing light-weight vs. heavy-weight mesh was ever made, much less that it was sent to Ethicon.

Plaintiffs' speculation that Ethicon lost "important information about Ethicon's marketing strategies and, most importantly, communications between [sales representatives] and treating physicians" (Mot. at 22) is similarly insufficient. For one thing, plaintiffs are wrong that Ethicon only has a "few" documents for the two sales representatives identified in their motion, Paul Courts and Troy Mohler. In addition to the hundreds of documents produced from their custodial files (Mittenthal Decl. ¶ 82), as set forth above, a search of Ethicon's production has revealed that the Company produced approximately 706 emails and attachments to or from Paul Courts and 2,375 emails and attachments to or from Troy Mohler from other employees' files. (Mittenthal Decl. ¶ 70.) Moreover, as Mr. Mittenthal has explained, it is "unsurprising . . . that relatively few documents were directly collected from" these individuals because the job of a medical device sales representative is not "document-intensive." (*Id.* ¶¶ 81-82.) And Ethicon did produce marketing materials given to physicians by sales representatives from other sources.

Finally, plaintiffs complain that the MedScand materials "are just gone" and cannot be found in any file at Ethicon. (Mot. at 24.) But, as set forth above, most of the MedScand materials that plaintiffs reference were either discarded at a time when there was no duty to preserve or lost in a fire at a third-party facility over which Ethicon had no control. Moreover, plaintiffs fail to explain how MedScand's expired product retains, which by their very nature are no longer usable and therefore have no purpose, could possibly have been relevant to their claims. In short, plaintiffs have nothing – other than rank speculation – to support their argument that any of the materials that were lost would have helped them at trial.

***Second***, even if the Court were to assume that the 22 employees identified in plaintiffs'

motion had electronic files on their hard drives that were relevant to this litigation, a substantial portion of these documents were also available and produced from other sources. As courts have recognized, spoliation sanctions are not appropriate where a party is accused of losing or destroying materials that are “cumulative” of other evidence already produced and therefore “not essential” to the case. *Reinsdorf v. Skechers U.S.A., Inc.*, No. CV 10-7181 DDP (SSx), 2013 U.S. Dist. LEXIS 107631, at \*82-83 (C.D. Cal. July 19, 2013); *Johnson v. Next Day Blinds Corp.*, No. WMN-09-2069, 2012 U.S. Dist. LEXIS 95800, at \*9 (D. Md. July 11, 2012) (rejecting spoliation claim where the missing documents were “largely cumulative” and any missing information could be “readily extrapolate[d]” from the documents that were produced).

That is precisely the case here. As set forth above and in the Mittenthal declaration, potentially relevant evidence located on the hard drives of the former employees was likely available in other, common-source locations within the Company and produced from those sources. (See Mittenthal Decl. ¶¶ 70-73.) And because Ethicon employees work collaboratively with one another, the Company has produced hundreds – and in most cases thousands – of emails and attachments sent or received by each of the 22 individuals identified in plaintiffs’ motion as having few or no electronic files.<sup>9</sup> (*Id.* ¶ 70.) For example, Ethicon has produced:

- 4,430 emails and attachments to/from Nancy Leclair;
- 5,578 emails and attachments to/from Zenobia Walji;
- 8,415 emails and attachments to/from Susan Landgrebe;
- 14,651 emails and attachments to/from Allison London Brown;

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<sup>9</sup> These emails almost certainly account for a significant percentage of the documents that would have been saved on these individuals’ lost hard drives. This is so because the overwhelming majority of documents in any given “custodial file” are emails, and even non-email documents are typically circulated by email and would therefore have been captured in the recipients’ files as email attachments.



- 5,520 emails and attachments to/from Cheryl Bogardus;
- 17,125 emails and attachments to/from Price St. Hilaire;
- 4,190 emails and attachments to/from Laura Angelini; and
- 8,503 emails and attachments to/from Renee Selman.

(*Id.*) Thus, “even where an individual’s ‘custodial file’ does not contain any documents,” it is likely that many of the “individual’s documents (including email communications) have been collected and produced” elsewhere. (*Id.* ¶ 73.) As Mr. Mittenthal has explained, this is especially true given the breadth of Ethicon’s collection in this litigation. Because Ethicon collected documents from a large number of custodians who worked directly with the individuals they have identified, as well as many common sources, the Company necessarily produced many of the allegedly “missing” documents related to these individuals from other sources. (*Id.* ¶¶ 75-79.) By way of example, Mr. Mittenthal points to emails sent to some of the individuals identified in plaintiffs’ briefing that were also sent to, and produced in, the custodial files of, on average, a dozen other Ethicon employees. (*Id.* ¶¶ 78-79.)

Plaintiffs argue that the Court “should not be swayed” by evidence that a large portion of the materials they claim were destroyed were actually “produced from other files” because it is *possible* that there are some documents that were not collected elsewhere. (Mot. at 23.) However, the fact that Ethicon has produced a significant number of documents pertaining to the 22 individuals identified in plaintiffs’ brief severely undercuts plaintiffs’ argument that Ethicon should be subject to severe sanctions because it has lost “thousands upon thousands” of documents essential to this case.<sup>10</sup> (*See id.* at 2-3.) And even if some documents included on the

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<sup>10</sup> Plaintiffs argue that “communications between an employee” – including “high-level people” such as Renee Selman – and an outside person would “obviously not be produced from another employee’s files.” (Mot. at 23.) In reality, however, it is highly unlikely that the worldwide president of a business unit, or any other individual

(*cont'd*)

hard drives at issue were not produced from other locations, plaintiffs have no evidence that any of those materials were relevant to their claims or would have been used at trial. For this reason too, plaintiffs' motion should be denied.

## **II. PLAINTIFFS' REQUESTS FOR EXTREME SANCTIONS SHOULD BE DENIED.**

Even if the Court were to find that some form of sanction were appropriate – which it should not – the sanctions sought by plaintiffs are far too drastic because Ethicon acted in good faith, and any lost documents have not prejudiced plaintiffs' ability to prosecute their claims.

### **A. Default Judgment Would Be Inappropriate Because There Is No Evidence Of Bad Faith Or Extreme Prejudice To Plaintiffs.**

As the Fourth Circuit has explained, default judgments must be “given [particular] scrutiny because they deal with ‘[a] party’s rights to a trial by jury and a fair day in court.’” *Bizprolink, LLC v. America Online, Inc.*, 140 F. App’x 459, 462 (4th Cir. 2005) (citation omitted). In particular, the “severe sanction” of judgment as a matter of law “is only appropriate if the conduct was ‘so egregious as to amount to a forfeiture of [the] claim,’ or if the effect of the conduct was ‘so prejudicial that it substantially denied the’ moving party the ability to pursue or defend a claim. *Loveless*, 232 F. App’x at 236 (quoting *Silvestri*, 271 F.3d at 593). As set forth more fully below, neither circumstance is present here.

**First**, Ethicon did not act in bad faith. A party has acted in bad faith for purposes of spoliation only if it has destroyed potential evidence in a purposeful effort to prevent the other

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employee, would be communicating with a third party regarding a product without copying or involving other Ethicon employees. (See Mittenthal Decl. ¶ 84 (noting that Ms. Selman has testified that “due to her position, she was not the author of many documents and that such documents likely would be associated with other individuals’ ‘custodial files’”).) Plaintiffs also argue that, despite the production of thousands of documents pertaining to the custodians at issue (see Mittenthal Decl. ¶ 70), they may have “missed documents due to not having an established custodial file for each witness” (Mot. at 23). This argument should also be rejected because reasonable searches of e-mail addresses and other similar queries would easily identify such documents. (See Mittenthal Decl. ¶ 70.)

side from obtaining it. *See, e.g., Cole v. Keller Indus., Inc.*, 132 F.3d 1044, 1047 (4th Cir. 1998) (no bad faith where actions by plaintiff's expert "were [not] undertaken in an effort to prevent the defendant from inspecting and testing the ladder"); *Loveless*, 232 F. App'x at 237 ("[t]here is no indication . . . that Brown's failure to preserve the worksheet was intended to deprive the jury or [opposing party] of any evidence"); *Hawkins v. Coll. of Charleston*, No. 2:12-cv-384-DCN, 2013 U.S. Dist. LEXIS 162714, at \*11 (D.S.C. Nov. 15, 2013) (refusing to impose dismissal sanction because, *inter alia*, "there is not sufficient evidence that Hawkins 'destroyed the evidence with the intention of depriving [the College] of the evidence'" (citation omitted)).

In *Cole*, for example, the plaintiff brought a product-liability suit against the manufacturer of an allegedly defective ladder. 132 F.3d at 1045. During the course of plaintiff's expert's investigation of the ladder, the expert removed one of the steps from the ladder, grounded off the heads of the rivets at the left front of that step, broke the right rivets, which he ultimately lost, and "hacksawed out a portion of the step surrounding the left rear rivet." *Id.* at 1046. The defendant moved for summary judgment based on plaintiff's spoliation, arguing that the destructive testing of the ladder prejudiced it. *Id.* The district court dismissed the case, but the Fourth Circuit reversed, explaining that "absent bad-faith conduct[,] applying a rule of law that results in [judgment as a matter of law] on the grounds of spoliation of evidence is not authorized." *Id.* at 1047. In so ruling, the court reasoned that while the plaintiff's expert destroyed portions of the ladder in the course of his investigation, there was "no evidence that [his] actions were undertaken in an effort to prevent the defendant from inspecting and testing the ladder." *Id.* Because the expert's "mistake" did not rise to the level of bad-faith conduct,

“[t]he remedy chosen by the district court was simply too severe.” *Id.*<sup>11</sup>

The same rationale applies here. As explained in Mr. Mittenthal’s declaration, “any losses of data” in this case “were attributable to some type of *misunderstanding* by an employee and/or a *miscommunication* between a departing employee and his or her manager.” (Mittenthal Decl. ¶ 86 (emphases added).) In other words, there was no selective, intentional destruction of documents known to be relevant to the subject matter of this litigation. (*Id.* ¶ 85; *see also* Decl. of Phu Dao ¶ 7 (attached as Ex. 5) (sworn statement that individual responsible for overseeing IT support for Ethicon was “not aware of anyone [involved in Ethicon’s IT department] having intentionally deleted or destroyed any data that was known at that time to be relevant to the Ethicon pelvic mesh litigation”).) Because there is no evidence that the “mistake[s]” at issue “were undertaken in an effort to prevent [plaintiffs] from” obtaining information relevant to their claims, *Cole*, 132 F.3d at 1047, plaintiffs cannot demonstrate bad faith and are not entitled to a default judgment.

Plaintiffs argue that the Court should nonetheless “infer bad faith” from the fact that electronic documents belonging to Renee Selman, the former president of Ethicon’s Women’s Health & Urology business, were not retained upon her departure from the Company. (Mot. at 18.) According to plaintiffs, the Court should assume “that there was . . . some very damaging information on that hard drive” that “would have been harmful to Ethicon in this litigation” or else Ethicon would not have “delete[d everything.” (*Id.*) However, plaintiffs do not have even one shred of evidence to support this serious allegation. Further, as stated above, James

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<sup>11</sup> “Most of the Fourth Circuit cases involving sanctions for spoliation of evidence arise in the context of a defendant asking for dismissal of a plaintiff’s claims because of destruction of evidence by the plaintiff.” *Sampson*, 251 F.R.D. at 180 n.11. However, “[b]ecause . . . rendering default judgment is equally as harsh a sanction as dismissing the case of a plaintiff with prejudice, [courts have] cite[d] cases involving these sanctions interchangeably.” *Id.* (quoting *Pressey v. Patterson*, 898 F.2d 1018, 1021 n.2 (5th Cir. 1990)).

Mittenthal, who investigated the loss of Ms. Selman's files, confirms that his investigation "did not identify a single instance in which an Ethicon employee selectively and intentionally destroyed documents known to be relevant to the pelvic mesh litigation." (Mittenthal Decl. ¶ 85.) Plaintiffs' argument that the "destruction of the Medscand data also evinces bad faith" because the "logical inference is that those boxes also contained harmful information" that Ethicon purposefully destroyed is similarly baseless. (Mot. at 18.) As set forth in detail above, there is no evidence whatsoever that Ethicon had anything to do with the fire *at a facility owned by a third party* that destroyed many of the MedScand documents – or that the expired product retains that were discarded had any use. Thus, plaintiffs' allegations of intentional document destruction are nothing more than figments of their own imagination.

*Second*, plaintiffs also cannot establish that Ethicon's alleged spoliation caused extreme prejudice. In cases devoid of bad faith, a default judgment is only proper where the loss of information substantially prejudiced the opposing party's ability to prosecute her case. *See Grayson Consulting*, 2013 U.S. Dist. LEXIS 107218, at \*22-23 ("The harsher sanctions of dismissal and default judgment require a showing of bad faith . . . unless the spoliation was so prejudicial that it prevents the non-spoliating party from maintaining his case.") (internal quotation marks and citation omitted). The touchstone of this inquiry is whether the lost information is so "central to the case" that the non-spoliating party does not have "*enough*" information to build her case. *See Hawkins*, 2013 U.S. Dist. LEXIS 162714, at \*10, \*13 (emphasis added) ("The record 'contain[s] enough data' for the College to build its defense. Therefore, content of Hawkins's Facebook page is not so central to the case that its destruction 'substantially denied the defendant the ability to defend the claim.'") (citations omitted). Accordingly, courts have routinely denied requests for the entry of judgment based on "[t]he

availability of other evidence to the moving party.” *Musick v. Dorel Juvenile Grp., Inc.*, No. 1:11CV00005, 2011 U.S. Dist. LEXIS 122580, at \*7 (W.D. Va. Oct. 24, 2011) (entry of judgment was not proper where moving party had sufficient evidence to make its case with regard to causation).

Here, there can be no dispute that plaintiffs have more than “*enough*” information to build their case against Ethicon. As set forth in Section I.C above, plaintiffs have extensive materials related to their claims, including adverse event reports, clinical trial data, regulatory documents, and marketing materials provided to doctors and patients. In addition, they also have hundreds or thousands of emails from each of the individuals at issue in plaintiffs’ motion. Given the substantial discovery provided to plaintiffs in this litigation, it is not surprising that they have been unable to identify any relevant evidence that is supposedly missing – let alone evidence “so central to the case” that they will be unable to present their claims at trial. Plaintiffs’ effort to turn some unfortunate mistakes into a windfall and avoid having to prove their claims at trial should be summarily rejected.

**B. An Adverse Jury Instruction Would Be Inappropriate.**

Plaintiffs’ request for an adverse-inference jury instruction should also be rejected. An adverse-inference instruction “creates a substantial danger of unfair prejudice” by “encourag[ing] the jury to speculate that the missing [information] contained admissions and other information damaging to” the party accused of spoliation. *Morris v. Union Pac. R.R.*, 373 F.3d 896, 903 (8th Cir. 2004); *see also id.* at 900-01 (“When giving such an instruction, a federal judge brands one party as a bad actor, guilty of destroying evidence that it should have retained for use by the jury.”). This prejudice is “all but a declaration of victory” for the opposing side. Laura A. Adams, *Reconsidering Spoliation Doctrine Through the Lens of Tort Law*, 85 Temp. L. Rev. 137, 151 (2013). Accordingly, a court may only permit the jury to draw an “adverse inference”

from a party's spoliation of evidence where the loss of evidence was more than just "negligent;" such an "inference requires a showing that the party knew the evidence was relevant to some issue at trial and that his willful conduct resulted in its loss or destruction.'" *Simms v. Deggeller Attractions, Inc.*, No. 7:12-cv-00038 et al., 2013 U.S. Dist. LEXIS 448, at \*17 (W.D. Va. Jan. 2, 2013) (quoting *Vodusek v. Bayliner Marine Corp.*, 71 F.3d 148, 156 (4th Cir. 1995)). That type of showing cannot be made where the loss of information resulted from mere "inadvertent oversight." See *Carter v. Farmer*, No. 7:12CV00008, 2012 U.S. Dist. LEXIS 127188, at \*12 (W.D. Va. Sept. 7, 2012) (adverse-inference instruction not proper where "the loss of the video resulted from . . . inadvertent oversight"), *aff'd*, 518 F. App'x 158 (4th Cir. 2013); see also *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, No. 3:09cv58, 2011 U.S. Dist. LEXIS 45888, at \*54 (E.D. Va. Apr. 27, 2011) ("There is no doubt that some unknown employee at DuPont or DKI deleted Tad Lee's email account on January 27, 2009, resulting in the loss of his emails. What Kolon has not shown, however, is that the employee intentionally or willfully deleted the account, rather than negligently, or that the employee or DuPont knew . . . that the emails were relevant to some issue at trial") (citation omitted).

As set forth in detail above, there is no evidence that the alleged loss of information was the result of anything other than an oversight by certain Ethicon employees who failed to follow the Company's policies with respect to document retention, most notably when they (or individuals working with them) left the Company. Such "inadvertent" conduct does not reflect knowledge by Ethicon that lost information was relevant to any issue in this litigation or establish that the Company willfully took steps to destroy it. As a result, plaintiffs' request for an adverse-inference instruction should also be denied.

**C. There Is No Basis For Striking Ethicon's Defenses.**

Plaintiffs' proposal to strike Ethicon's statute-of-limitations and learned-intermediary defenses should also be rejected. As courts have noted, because "the purpose of imposing sanctions is to punish and deter, rather than to reward [a party] with some windfall," striking defenses is only appropriate where the lost information actually "would support those defenses." *Alden v. Mid-Mesabi Assocs. Ltd. P'ship*, No. 06-954 (JRT/RLE), 2008 U.S. Dist. LEXIS 123190, at \*17 (D. Minn. Feb. 25, 2008) (declining to strike plaintiff's affirmative defenses to counterclaims because the defendants could not establish that the lost information was sufficiently probative of those defenses); *see also Davis v. Ford Motor Co.*, 375 F. Supp. 2d 518, 521-22 (S.D. Miss. 2005) (denying motion to strike defendant's defenses based on lack of testing and analysis of spoliated vehicle because "plaintiffs' inability to inspect, view or test the actual vehicle involved in this particular rollover accident cannot have impaired their ability to establish their claim based on the alleged design defect in the handling and stability of the Explorer").

Here, plaintiffs cannot establish that any of the lost information has anything to do with Ethicon's defenses. For example, plaintiffs assert that the Court should strike Ethicon's learned-intermediary defense because Ethicon "should not be permitted to argue" that it adequately warned doctors about the risks of pelvic mesh when "information [is] missing from so many of the sales representatives and other marketing witnesses" about what was said to doctors. (Mot. at 25.) But, as set forth above, medical device sales representatives typically do not maintain such documents. (Mittenthal Decl. ¶¶ 81-82.) Thus, there is no reason to believe that the files of sales representatives would have contained relevant information about their communications with physicians, and marketing materials provided to physicians by sales representatives would have been produced from other sources.

At the very least, even if plaintiffs' argument had potential merit, they would need to



show that documents purportedly relevant to the learned-intermediary defense are missing in a specific case. Needless to say, plaintiffs are free to depose all of the relevant physicians in all the pelvic mesh cases and ask them about their interactions with sales representatives and what sorts of marketing materials they received and/or relied on. They are also free to depose any former employees regarding their communications with doctors and to determine whether any allegedly relevant documents are missing. Plaintiffs have not identified any physician in any case who was allegedly influenced by marketing materials or communications that they allege are not available. For all of these reasons, plaintiffs' request to strike Ethicon's learned-intermediary defense should be rejected.

Plaintiffs are also unable to tie Ethicon's statute-of-limitations defense to the alleged spoliation of documents. According to plaintiffs, Ethicon should not be allowed to invoke a limitations defense because "fraudulent concealment generally will toll the statute of limitations," and it is *possible* that lost documents could "demonstrate deception of consumers." (Mot. at 25.) But in order to prove fraudulent concealment, plaintiffs would have to show that Ethicon took affirmative steps to prevent them from discovering that they had a cause of action against Ethicon, even though they exercised due diligence to discover their claims. *Martin v. Grehn*, No. 13-50070, 2013 U.S. App. LEXIS 19639 (5th Cir. Sept. 25, 2013). In other words, fraudulent concealment tolls claims where there were misstatements *after* the alleged tort occurred – not before. Thus, even if there were evidence that the 22 employees identified in plaintiffs' brief had documents about improper marketing that somehow did not make it into anyone else's files in the entire Company – and there is not – it still would not prove that Ethicon made fraudulent statements to plaintiffs that prevented them from filing suit in a timely manner.

At bottom, plaintiffs are not seeking relief that has any relationship to the lost documents.

Instead, they have simply selected two defenses that they believe will pose the greatest challenge to them at trial and have sought to deprive Ethicon of those defenses in order to give themselves a strategic advantage at trial. For this reason too, the motion should be denied.

**D. Monetary Sanctions, If Any, Should Be Limited To The Expenses Incurred By Plaintiffs In Deposing Ethicon's Corporate Representative And Preparing Their Motion.**

As set forth in detail above, the unintentional loss of documents – much of which occurred before this litigation even began – does not warrant any sanctions. However, Ethicon does recognize that some documents were inadvertently lost, causing both parties to incur additional expenses in discovery. As noted above, Ethicon takes this issue very seriously. For this reason, Ethicon's counsel have worked with plaintiffs for months in an effort to investigate why certain employees' documents were not preserved and determine whether those documents have been produced to plaintiffs from other sources. In addition, promptly after discovery of this issue, Ethicon instituted a number of internal procedures that are designed to minimize the risk that documents potentially relevant to litigation are lost going forward. In short, Ethicon has done everything it reasonably could to rectify the situation and ensure that it does not happen again.

In light of these efforts – as well as the inadvertent nature of the loss of documents and the lack of prejudice to plaintiffs – Ethicon believes that, to the extent the Court finds any sanction to be appropriate, it should be limited to a monetary sanction equal to plaintiffs' expenses related to: (1) the depositions of Ethicon's corporate representative regarding document retention issues; and (2) the preparation of plaintiffs' motion for sanctions.

**CONCLUSION**

For all of the reasons set forth above, the Court should deny plaintiffs' motion.

Dated: January 10, 2014

Respectfully submitted,

ETHICON, INC. AND  
JOHNSON & JOHNSON

/s/ David B. Thomas

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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

-----X	
<b>IN RE ETHICON, INC., PELVIC REPAIR</b>	<b>:</b> <b>CIVIL ACTION NO. 2:12-md-02327</b>
<b>SYSTEM PRODUCTS LIABILITY</b>	<b>:</b>
<b>LITIGATION</b>	<b>:</b> <b>MDL No. 2327</b>
-----	<b>:</b>
	<b>:</b> Judge Joseph R. Goodwin
This Document Applies To All Actions	<b>:</b>
	<b>:</b>
-----X	

**CERTIFICATE OF SERVICE**

I, David B. Thomas, certify that on January 10, 2014, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

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